STATE OF MISSOURI
MISSOURI BOARD OF PHARMACY

IN RE:	)	
	)	
CANTRELL DRUG COMPANY, INC.	)	Complaint No. 2018-00192
7321 Cantrell Road, Ste. 300-400	)	
Little Rock, AR 72207	)	
Permit No. 2010023401	)	

SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY AND CANTRELL DRUG COMPANY, INC.

COME NOW Cantrell Drug Company, Inc. ("Respondent" or "Cantrell") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's permit to operate as a drug distributor will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri ("AHC") and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proved upon the record by competent and substantial evidence; the right to cross-examine any witness appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against its permit. Being aware of these rights provided it by operation of law, Respondent knowingly and

voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document as they pertain to it.

Respondent acknowledges that it has received a copy of the draft complaint to be filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's permit.

For purposes of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true, stipulates with the Board that Respondent's permit as a drug distributor, numbered 2010023401, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo.

JOINT STIPULATION OF FACTS

1. The Missouri Board of Pharmacy (the "Board") is an agency of the State of Missouri created and established pursuant to §338.110, RSMo[1], for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Respondent Cantrell Drug Company, Inc., 7321 Cantrell Road, Ste. 300-400, Little Rock, AR 72207, is an outsourcing facility under 21 U.S.C. § 353b.

3. Cantrell is permitted by the Board as a drug distributor under permit number 2010023401 issued on November 1, 2017. Respondent's permit was at all times relevant herein current and active.

4. In or around June 2017, the United States Food and Drug Administration ("FDA") conducted an inspection of Cantrell.

5. At the conclusion of the inspection, the FDA investigator issued Cantrell a Form 483 which detailed observations relating to its sterile compounding practice that, in the judgment

[1] All statutory references are to the Revised Statutes of Missouri 2016, as amended, unless otherwise stated.

of the investigator, constituted violations of the Food Drug and Cosmetic Act and other federal acts.

6. The observations included:

A. misreading of agar plates for environmental and personnel monitoring results;

B. lack of quality control related to good documentation practices (incidences of original documents found in the shred bin and appearance of altering manufacturing records);

C. deficiencies regarding air supply and loss of positive airflow (repeat violation);

D. issues related to cleanroom design (gaps around HEPA filters, cracks, and possible impediment of air flow);

E. failure to thoroughly review unexplained discrepancies and its impact on a batch (e.g., during periods of environmental excursions, sterility testing discrepancies where "user abort" events occurred, and HEPA filter leaks);

F. aseptic technique violations (operator's head entering ISO 5 area);

G. media fill did not simulate the most complicated process of production (testing did not simulate the use of stored concentrate during processing);

H. failure to establish an SOP for terminal cleans and no documentation of terminal cleans;

I. failure to follow manufacturer's contact time for cleaning/sporicidal agents (repeat violation);

J. endotoxin amount in the drug products was not tested throughout the shelf life in the stability studies; and

K. labels were deficient in that they did not include the statement "this is a compounded drug" (repeat violation).

7. Cantrell denies that it has violated any aspect of the law or regulations of the FDA relating to its production of sterile drugs.

8. Cantrell conducted a voluntary recall on or about July 25, 2017 of all sterile compounded drugs distributed between February 16, 2017 and July 19, 2017 and ceased all sterile compounding activities on July 21, 2017 while it addressed the FDA's concerns.

9. Cantrell distributed 23,725 compound preparations in the State of Missouri that were affected by this recall.

10. Cantrell resumed compounding on July 28, 2017.

11. Previously, Cantrell received an FDA Form 483 following an FDA inspection in October, 2016 which also resulted in Cantrell ceasing its operations from November 2, 2016 to December 15, 2016 and conducted a voluntary recall of certain sterile drug products.

12. As a result of the October, 2016 inspection, the South Carolina Board of Pharmacy entered an Order dated September 17, 2017, placing Cantrell's permit on probation for a minimum of two years.

13. Also a result of the October, 2016 and the June 19, 2017 inspections, the Alabama State Board of Pharmacy suspended Cantrell's permit on an emergency basis without a hearing on October 5, 2017, citing violations of 21 U.S.C. §§ 351 and 353b.

14. Respondent has been placed on probation and had its license/permit suspended in multiple states in violation of §338.055.2(8), RSMo.

JOINT CONCLUSIONS OF LAW

15. As a result of the foregoing sterile compounding violations and disciplinary action in multiple states, cause exists for Petitioner to take disciplinary action against Respondent's drug distributor permit under § 338.055.2(5), (6), (8), (13) and (15), RSMo, which provides:

> 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:
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> (5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;
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> (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;
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> * * *
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> (8) Denial of licensure to an applicant or disciplinary action against an applicant or the holder of a license or other right to practice any profession regulated by this chapter granted by another state, territory, federal agency, or country whether or not voluntarily agreed to by the licensee or applicant, include, but not limited to, surrender of the license upon grounds for which denial or discipline is authorized in this state;
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> (13) Violation of any professional trust or confidence;
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> * * *
>
> (15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government.

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.3, RSMo:

1. Respondent's drug distributor permit numbered 2010023401 shall be placed on **PROBATION** for a period of **THREE (3) YEARS** ("disciplinary period"). The period of probation shall constitute the disciplinary period. The terms of discipline shall be as follows:

A. Respondent shall pay all required fees for licensing to the Board and shall renew its drug distributor license prior to October 31 of each licensing year.

B. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

C. If, after disciplinary sanctions have been imposed, the Respondent fails to keep its drug distributor license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

D. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after this Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of its disciplinary order.

E. Respondent shall make a representative of the drug distributor available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Respondent will be notified and given sufficient time to arrange these meetings.

F. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Agreement.

G. The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

2. Upon the expiration of said discipline, Respondent's license as a drug distributor in Missouri shall be fully restored if all other requirements of law have been satisfied provided, however, that in the event the Board determines that the Respondent has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline the Respondent.

3. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

4. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

5. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

6. Respondent hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs, and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. §1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,

_____REQUESTS

JLM DOES NOT REQUEST

THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S PERMIT TO OPERATE AS A PHARMACY.

Respondent understands that it may, either at the time the Settlement Agreement is signed by all parties, or within fifteen (15) days thereafter, submit the Settlement Agreement to the Administrative Hearing Commission for determination that the facts agreed to by the parties constitute grounds for disciplining Respondent's permit. If Respondent desires the Administrative Hearing Commission to review this Agreement, it may submit its request to: Administrative Hearing Commission, Truman State Office Building, Room 640, 301 W. High Street, P.O. Box 1557, Jefferson City, Missouri 65101.

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement Agreement goes into effect fifteen (15) days after the document is signed by the Board's Executive Director.

RESPONDENT

CANTRELL DRUG COMPANY, INC.

By: _____

Dell McCarley,
Authorized Agent for
CANTRELL DRUG
COMPANY, INC.

Printed: Dell McCarley

Date: 1-22-2019

PETITIONER

MISSOURI BOARD OF PHARMACY

By: _____

Kimberly Grinston
Executive Director

Date: 2-20-19

NEWMAN, COMLEY & RUTH P.C.

By: _____

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